

Accessing Structured Product Labeling Data Via Mobile Devices

September 2012

Lonnie Smith
Policy Analyst
U.S. FDA Data Standards Council



Overview

- SPL Standard
- Exchange of SPL Data
- Accessing SPL Data Via Mobile Devices

SPL Standard

- HL7 health and regulatory data international standard
- Adopted by FDA
- Exchange of product and facility information
- Current use at FDA:
 - Initiative to improve patient safety through better access to product information
 - Drug product information (Rx and OTC human and animal drug products)
 - Drug establishment registration
 - Indexed clinical data (e.g. pharmacologic class, indications)
 - Inserted machine readable tags not in printed content of labeling
 - Allows users to rapidly search and sort information
 - Support automated health information systems
 - Electronic health records, electronic prescribing, clinical decision support systems

SPL Received from Locations in Over 80 Countries



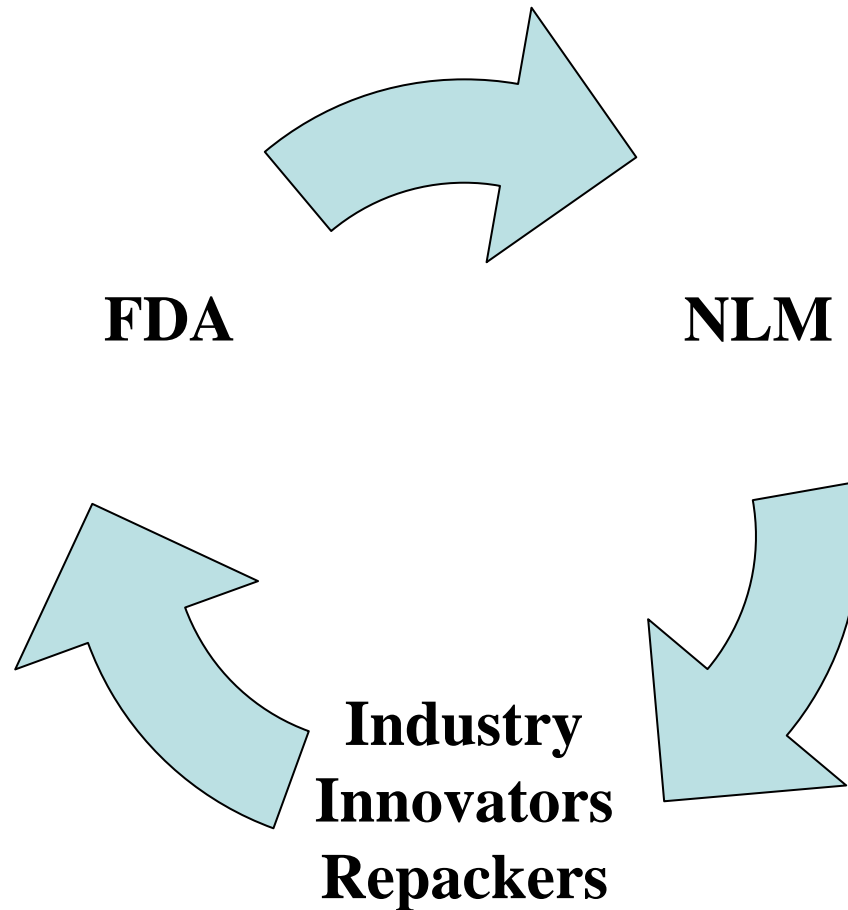
- Owners/operators of drug establishments around the globe which commercially market drug products in the US register sites in SPL format
- SPL files are submitted for drug products manufactured at these facilities.

Multiple Purposes for SPL File

- One Content of Labeling SPL File –
Companies may fulfill multiple regulatory obligations and other purposes
 - Content of labeling (compliance with Electronic Labeling Rule)
 - Drug Listing (compliance with FDAAA 2007)
 - Electronic label published in public repository
 - Downloaded into healthcare information systems

Exchanging SPL Data

Exchanging SPL Data



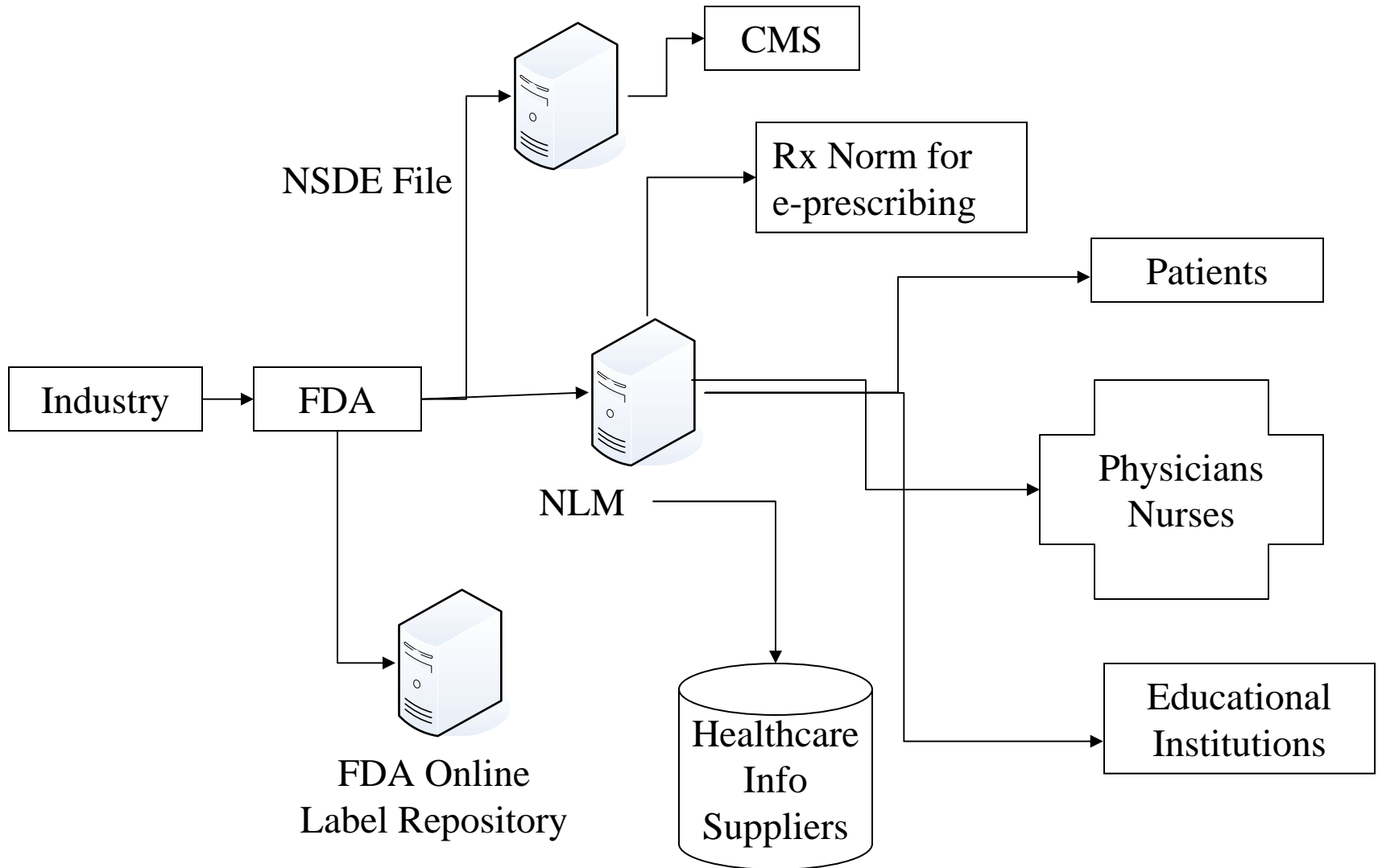
Types of SPL Product Data Exchanged

- Drug Products
 - Human Rx Drugs
 - Approved & Unapproved Rx drugs
 - Unapproved medical gases
 - Unapproved homeopathic
 - Human OTC Drugs
 - OTC monograph final
 - OTC monograph not final
 - OTC homeopathic
 - Animal Rx drugs
 - Approved Rx
 - Unapproved Rx
 - Animal OTC Drugs
- Others
 - Medical device (content of labeling) (Voluntary submissions only)
 - Medical foods (Voluntary submissions only)
 - Dietary Supplements (Voluntary submissions only)

Components of Exchanged SPL Files

- Components
 - Content of labeling (e.g. package inserts, drug facts)
 - Product data elements
 - Images (chemical structures, graphs, products)

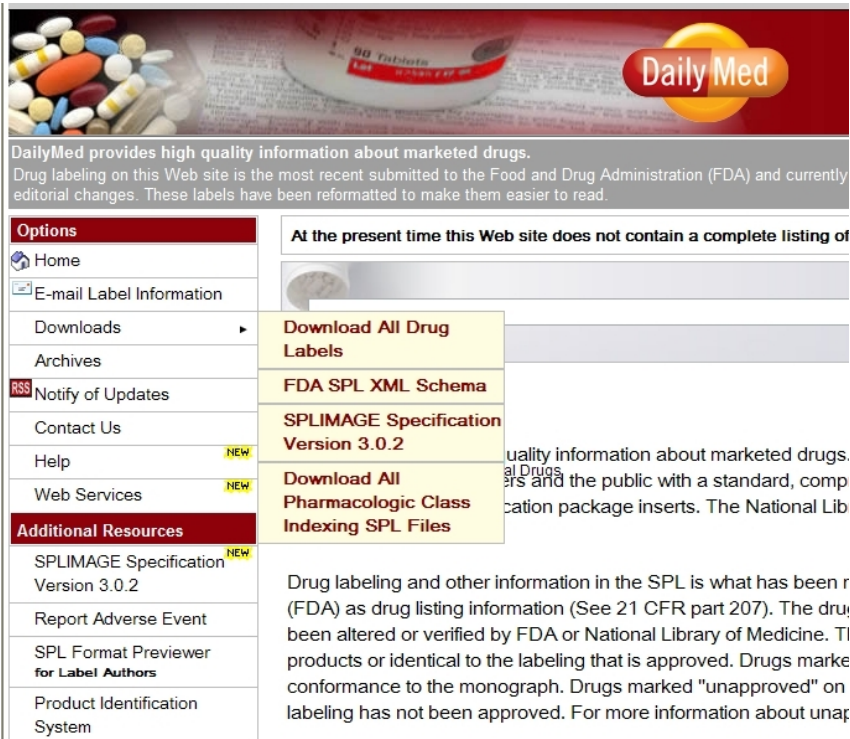
Data Sharing



Accessing SPL Data Via Mobile Devices


DailyMed

- FDA-to-NLM - Daily transmissions of up-to-date product information received from drug companies
- MOU (FDA/NLM)
- NLM makes all SPL files available via download



The image shows a screenshot of the DailyMed website. The header features a banner with various pills and a 'DailyMed' logo. Below the banner, a text box states: 'DailyMed provides high quality information about marketed drugs. Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently editorial changes. These labels have been reformatted to make them easier to read.' The navigation menu on the left includes 'Options' (Home, E-mail Label Information, Downloads, Archives, Notify of Updates, Contact Us, Help, Web Services) and 'Additional Resources' (SPLIMAGE Specification Version 3.0.2, Report Adverse Event, SPL Format Previewer for Label Authors, Product Identification System). A central message box reads: 'At the present time this Web site does not contain a complete listing of' followed by a list of links: 'Download All Drug Labels', 'FDA SPL XML Schema', 'SPLIMAGE Specification Version 3.0.2', and 'Download All Pharmacologic Class Indexing SPL Files'. A partial text box on the right mentions 'quality information about marketed drugs'.

DailyMed Mobile



Search:

Limit:

DRUG

NDC

CLASS

SETID

Label Type:

HUMAN

ANIMAL

GO

About DailyMed

[Copyright](#) | [Privacy](#) | [Accessibility](#) | [Contact Us](#)



U.S. National Library of Medicine
National Institutes of Health
Department of Health & Human Services

Visit the Full DailyMed Site
(not optimized for mobile devices)


- NLM's version of their DailyMed website optimized for mobile devices

DailyMed Mobile

Content of Labeling




CYMBALTA (duloxetine hydrochloride) capsule, delayed release
[Eli Lilly and Company]


 HIGHLIGHTS OF PRESCRIBING INFORMATION

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Cymbalta is not approved for use in pediatric patients [see *Warnings and Precautions* (5.1), *Use in Specific Populations* (8.4), and *Information for Patients* (17.2)].

 1 INDICATIONS AND USAGE

 2 DOSAGE AND ADMINISTRATION

 3 DOSAGE FORMS AND STRENGTHS

- Mobile version of DailyMed – permits expansion of certain sections of labeling instead of all.

DailyMed Mobile

Image of Container Label



- Permits users to view updated representative samples of carton/container label

DailyMed Mobile RxNorm (ePrescribing)

RxNorm	
RXNORM NAMES	RXCUI
Cymbalta 20 MG (duloxetine hydrochloride 22.4 MG) Enteric Coated Capsule	596928
Cymbalta 20 MG Enteric Coated Capsule	596928
duloxetine 20 MG (duloxetine HCl 22.4 MG) Delayed Release Capsule	596926
Cymbalta 60 MG (duloxetine hydrochloride 67.3 MG) Enteric Coated Capsule	615186
duloxetine 60 MG (duloxetine hydrochloride 67.3 MG) Delayed Release Capsule	596934
Cymbalta 30 MG (duloxetine hydrochloride 33.7 MG) Enteric Coated Capsule	596932
Cymbalta 30 MG Enteric Coated Capsule	596932

- View RxNorm names and codes for products

DailyMed Mobile

Structured Product Data Elements

CYMBALTA

duloxetine hydrochloride capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0002-3235
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Duloxetine hydrochloride (Duloxetine)	Duloxetine	20 mg

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

Gelatin

Hypromelloses

HYPROMELLOSE ACETATE SUCCINATE 16070722 (3 MM2/S)

Sodium lauryl sulfate

Sucrose

Talc

Titanium dioxide

Triethyl citrate

FD&C BLUE NO. 2

FERRIC OXIDE YELLOW

Product Characteristics

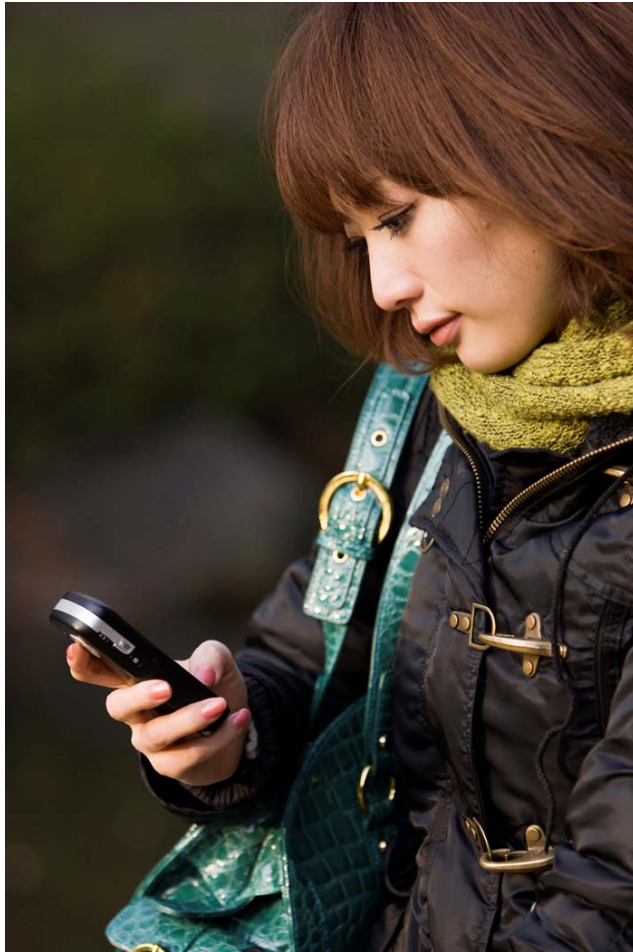
Color	green (opaque green)	Score	no score
Shape	CAPSULE	Size	15mm

DailyMed Mobile Product Image



- Companies may now voluntarily provide images of their solid oral dosage form products via SPL files.
- Identification of products by consumers or poison control centers.

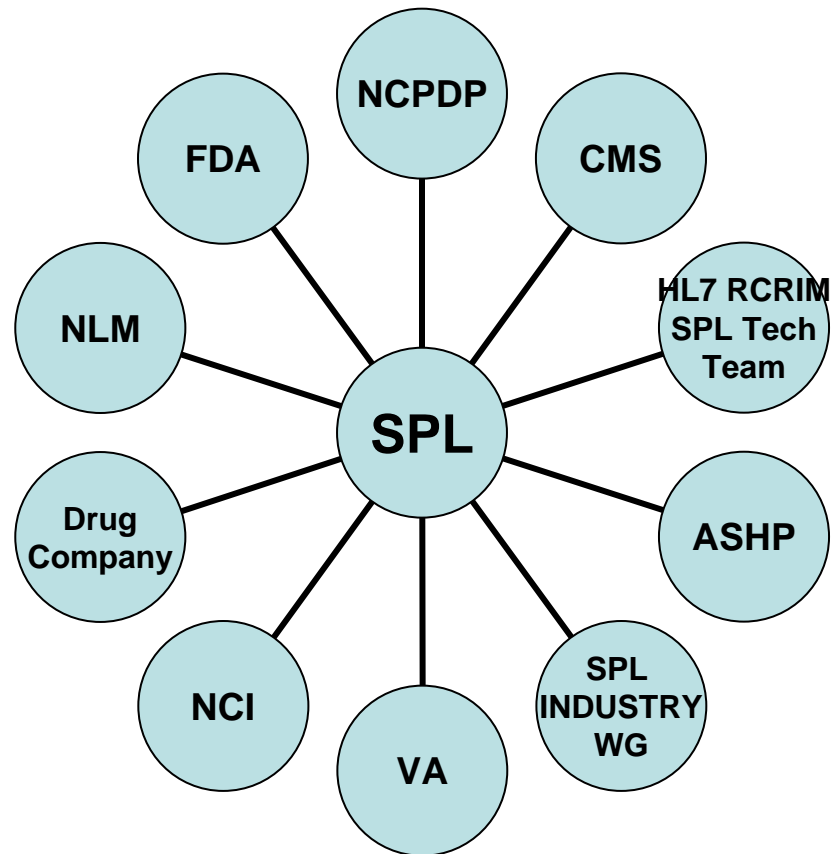
Consumers: Access to Up-to-Date Drug Product Information



- Access to same package insert info available to healthcare professionals
- Can review labels while awaiting filling of prescription.
- Updated medication guides, etc...
- Access to updated drug facts labels for OTC drug products

Other SPL-related Topics

Collaboration = SPL Success



Accomplishments

- FDA has been using the SPL standard for over 6 years
- DailyMed –
 - **September 2012** – over **10 million** visits per month
- Unique SPL documents posted on DailyMed
 - **September 2012** – over **40,000**

Stay Informed

- FDA Data Standards Council website listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is a blue header for the U.S. Department of Health & Human Services with the website address www.hhs.gov. Below this is the FDA logo and the text "U.S. Food and Drug Administration". A navigation bar contains links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. A search bar and an "A-Z Index" button are also present. The main content area is titled "For Industry" and includes a breadcrumb trail: Home > For Industry > Data Standards. On the left is a sidebar menu for "Data Standards" with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled "FDA Resources for Standards" and features a sign-up link for email updates, a paragraph describing the council's role, and a link to "Structured Product Labeling".

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

Sign up for email updates.

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

Structured Product Labeling

SPL-related Questions

- SPL e-mail account (spl@fda.hhs.gov)

Thank You